

Citation:

Appel LJ, Sacks FM, Carey VJ, Obarzanek E, Swain JF, Miller ER 3rd, Conlin PR, Erlinger TP, Rosner BA, Laranjo NM, Charleston J, McCarron P, Bishop LM; OmniHeart Collaborative Research Group. Effects of protein, monounsaturated fat, and carbohydrate intake on blood pressure and serum lipids: results of the OmniHeart randomized trial. *JAMA*. 2005 Nov 16;294(19):2455-64.

PubMed ID: [16287956](#)

Study Design:

Randomized Crossover Trial

Class:

A - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compare the effects of 3 healthful diets, each with reduced saturated fat intake, on blood pressure and serum lipids.

Inclusion Criteria:

- Healthy adults, age 30 or older
- Individuals with stage 1 HT or prehypertension, with systolic blood pressure of 120 - 159 or diastolic blood pressure of 80 - 99 mm Hg.

Exclusion Criteria:

- Diabetic
- Active or prior CVD
- Very high LDL cholesterol
- Elevated TG levels
- Weight above 350 pounds
- Taking medicine that affects blood pressure or blood lipids
- Unwillingness to stop taking vitamin and mineral supplements or drink less than 14 drinks per week

Description of Study Protocol:

Recruitment: Mass mailing of brochures and advertisements were the primary recruitment strategies in the Baltimore, Maryland and Boston, Massachusetts area.

Design - Randomized, 3-period, crossover trial

Blinding used (if applicable) staff members were not blinded. Participants and personnel involved in data collection were blinded to diet sequence.

Intervention (if applicable)

- Three diets for 6 weeks each: a diet rich in carbohydrates, a diet rich in protein (about half from plant sources), and a diet rich in unsaturated fat (predominantly monounsaturated fat)
- Each diet was reduced in SFA, cholesterol, and sodium and rich in fruits, vegetables, fiber, potassium, and other minerals at the recommended levels.
- After a 6-day run-in period, in which participants ate 2 days of meals from each study diet, they were randomly assigned to 1 of 6 sequences of the 3 diets
- A washout period of 2 to 4 weeks separated the feeding periods
- During the washout period, participants ate their own food

Statistical Analysis

- Means and standard deviations.
- Difference testing for the three diets was performed among the measurements pertinent to the study.
- Nonparametric Wilcoxon rank-based and permutation-based tests were performed.
- Analysis of covariance was used to assess the effects of weight change on trial outcomes.
- Average 10-year risks for CHD were calculated using the the Framingham risk equation and the prospective Cardiovascular Munster risk equation.

Data Collection Summary:

Timing of Measurements

- Blood pressure was measured at each screening test and at one visit during the run-in period.
- During the feeding period, blood pressure was measured at one visit each week during the first four weeks and at five visits during the last 10 days.
- Blood samples were collected during a screening visit and at weeks 4 and 6 of each feeding period.
- Urine samples were obtained at baseline prior to feeding and once during the last 2 weeks of each feeding period.

Dependent Variables

- Blood pressure
- Serum lipids: LDL cholesterol, triglycerides and other CV risk factors

Independent Variables

- Three diets for 6 weeks each: a diet rich in carbohydrates, a diet rich in protein (about half from plant sources), and a diet rich in unsaturated fat (predominantly monounsaturated fat)

Control Variables

- Each diet was reduced in SFA, cholesterol, and sodium and rich in fruits, vegetables, fiber, potassium, and other minerals.

Description of Actual Data Sample:

Initial N: 191 randomly assigned to diet sequences.

Attrition (final N): 161 included in data analysis; 164 persons completed 2 feeding periods and 159 completed 3 diet periods.

Age: 30 and above; average age 53.6 years.

Ethnicity: 55% African American, 40% non-Hispanics, 5% other.

Other relevant demographics: 80% had some college or were college graduates. 67% had an annual income of \$30,000 or higher.

Anthropometrics 21% not overweight or obese, 34% overweight, and 45% obese.

Location: Baltimore, MD or Boston, MA

Summary of Results:

Key Findings

- Blood pressure, low-density lipoprotein cholesterol, and estimated CHD risk were lower on each diet compared to baseline.
- Compared with the carbohydrate diet, the protein diet further decreased mean systolic blood pressure by 1.4 mm Hg ($P = 0.002$) and by 3.5 mm Hg ($P = 0.006$) among those with hypertension and decreased LDL-cholesterol by 3.3 mg/dL (0.09 mmol/L, $P = 0.01$), HDL cholesterol by 1.3 mg/dL (0.03 mmol/L, $P = 0.02$), and triglycerides by 15.7 mg/dL (0.18 mmol/L, $P < 0.001$).
- Compared with the carbohydrate diet, the unsaturated fat diet decreased systolic blood pressure by 1.3 mm Hg ($P = 0.005$) and by 2.9 mm Hg among those with hypertension ($P = 0.02$), had no effect on LDL cholesterol, increased HDL cholesterol by 1.1 mg/dL (0.03 mmol/L, $P = 0.03$) and lowered triglycerides by 9.6 mg/dL (0.11 mmol/L, $P = 0.02$).
- Compared with the carbohydrate diet, estimated 10-year CHD risk was lower and similar on the protein and unsaturated fat diets.

Author Conclusion:

In conclusion, in the setting of recommended levels of saturated fat, cholesterol, fiber, fruit, vegetables, and minerals, diets that partially replace carbohydrates with protein or monounsaturated fat can further lower blood pressure, improve lipid risk factors and reduce CVD risk.

Reviewer Comments:

Relatively large sample size for crossover feeding study, and little attrition. Authors note the following limitations:

- *Duration of each diet was only 6 weeks*
- *Trial did not adjust for multiple comparisons*
- *Trial outcomes were CVD risk factors, not clinical events*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

- | | | |
|----|---|-----|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

Validity Questions

- | | | |
|------|---|-----|
| 1. | Was the research question clearly stated? | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| 2. | Was the selection of study subjects/patients free from bias? | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |
| 2.3. | Were health, demographics, and other characteristics of subjects described? | Yes |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | Yes |
| 3. | Were study groups comparable? | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | Yes |

3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blinding used to prevent introduction of bias?	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes

6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	???
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes

8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	???
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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